FEB 2 3 2012

Appendix 3: 510(k) Summary

As Required by 21 CFR 807.92

Submitter:	Anulex Technologies, Inc. 5600 Rowland Road, Suite 280 Minnetonka, MN 55343
Contact Person:	Rachel Kennedy Director, Regulatory Affairs and Quality Systems Anulex Technologies, Inc. Direct: 952.224.4034 Fax: 952.224.4040 E-Mail: rkennedy@anulex.com
Date Prepared:	February 21, 2012
Trade Name:	fiXate Tissue Band
Classification:	II
Product Code:	GZB 21 CFR 882.5880
Predicate Device(s):	The subject device is substantially equivalent to the following predicate devices: • Anulex Technologies fiXate Tissue Band, FB-100-01 (K111462 cleared September 8, 2011) • Anulex Technologies fiXate Tissue Band, FB-101-01 (K112849 cleared October 27, 2011) • Anulex Technologies fiXate Tissue Band, FB-102-01 (K113400 cleared December 16, 2011) • Ethicon, Inc., Ethibond Suture
Device Description:	The fiXate Tissue Band consists of an adjustable loop of non-absorbable 2-0 suture (UHMWPE or PET (coated or uncoated)) with two (2) attached anchors (PEEK Optima LT1 or PET). The construct is provided sterile and preloaded on a disposable delivery instrument. The instrument's needle facilitates placement of the suture by positioning the T-anchors in the sub-layer of tissue.
Indications for Use:	The fiXate Tissue Band is intended to be an accessory to the leads/catheter component of Spinal Cord Stimulator/Pain Pump systems functioning to secure the lead to the fascia or inter-spinous/supra-spinous ligament.

Functional and Safety Testing:	Biocompatibility testing was completed in accordance with ISO 10993-1 standards. Tensile testing was performed to verify compliance with USP suture requirements and a comparison of fixation strength was completed to support the safety and effectiveness of the fiXate Tissue Band.
Comparison to Predicate:	The fiXate Tissue Band that is the subject of this submission has identical technological characteristics in comparison to the previously cleared fiXate Tissue Band. The intended use is unchanged, fixation of implant components to the fascia or inter-spinous/supra-spinous ligament.
Conclusion:	Substantial equivalence is demonstrated through the detailed device description, performance testing and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 2 3 2012

Anulex Technologies, Inc.
% Ms. Rachel Kennedy
Director, Regulatory Affairs and
Quality Systems
5600 Rowland Road, Suite 280
Minnetonka, Minnesota 55343

Re: K113805
Trade/Device Name: fiXate Tissue Band
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted spinal cord stimulator for pain relief
Regulatory Class: Class II
Product Code: GZB, GAT
Dated: December 22, 2011
Received: December 23, 2011

Dear Ms. Kennedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

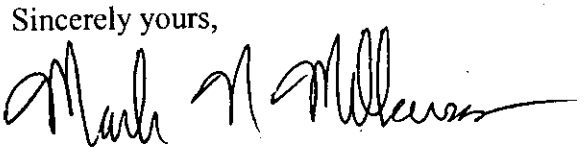
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 4: Indications for Use Form

Device Name: fiXate Tissue Band

Indications for Use:

The FiXate Tissue Band is intended to be an accessory to the leads/catheter component of Spinal Cord Stimulator/Pain Pump systems functioning to secure the lead to the fascia or inter-spinous/supra-spinous ligament.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113805